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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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(54) Title: MODIFIED RELEASE, MULTIPLE UNIT DRUG DELIVERY SYSTEMS

(57) Abstract: The invention relates to novel modified release multiple unit systems, and methods of preparing these systems, which can be easily compressed into tablets or filled into capsules or sachets without affecting the desired release characteristics of the pharmaceutical active ingredients incorporated within the systems. The multiple unit tablet includes multiple units. Each unit includes at least one core having an outer surface, a first coating layer surrounding at least a portion of the outer surface of the core and having an outer surface, one or more rate controlling polymers, and one or more active pharmaceutical ingredients. The coating layer includes one or both of the one or more active pharmaceutical ingredients and the one or more rate controlling polymers. The tablet may further include an outer layer on the outer surface of the unit which includes a material that is one or both of elastic and compressible. The material may be a wax materials, such as polyethylene glycol's (PEGs).

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## INTERNATIONAL SEARCH REPORT

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## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K9/24 A61K9/26 A61K9/28 A61K9/52 A61K31/4965  
A61K31/137

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, EMBASE, BIOSIS, MEDLINE

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99/12524 A (NYCOMED DANMARK A S ; BERTELSEN POUL (DK); SKINHOEJ ANNETTE (DK)) 18 March 1999 (1999-03-18)  example 1 claim 51 page 33, line 31 - line 35 ----- US 4 713 248 A (KJORNAES KIM ET AL) 15 December 1987 (1987-12-15) cited in the application  examples 2,7 abstract ----- -/-	1-9, 12, 29-35, 37-39, 68-70, 73, 76, 77
X	-----	1-4, 6-9, 12, 37, 38, 68, 69, 73, 76

 Further documents are listed in the continuation of box C. Patent family members are listed in annex.

## \* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*&\* document member of the same patent family

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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 783 215 A (ARWIDSSON HANS ET AL) 21 July 1998 (1998-07-21) cited in the application  claim 1 examples 1,5 -----	1,4-6,9, 13,14, 29,30, 32,33, 37,38, 68,69, 73,76
X,P	WO 03/041692 A (KARMA PHARM LTD ; SELA YORAM (IL)) 22 May 2003 (2003-05-22)  examples 1-4 claims 1,6 -----	1,4-11, 13,14, 29,30, 32,73, 108

**INTERNATIONAL SEARCH REPORT**

P B 03/02186

**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:  
Although claims 73-77 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the composition.
2.  Claims Nos.: 1, 41 (part.), 68, 73 (part.), 82 because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:  
see FURTHER INFORMATION sheet PCT/ISA/210
3.  Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1.  As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.  As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4.  No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-14, 18-40, 41-67 (part), 68-72, 73-77 (part), 101-103, 108-109, 114-117

**Remark on Protest**

The additional search fees were accompanied by the applicant's protest.  
 No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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Continuation of Box I.2

Claims Nos.: 1, 41 (part.), 68, 73 (part.), 82

Present claims 1, 41 (part.), 68, 73 (part.) and 82 relate to an extremely large number of possible compounds and products. Support within the meaning of Article 6 PCT and disclosure within the meaning of Article 5 PCT is to be found, however, for only a very small proportion of the compounds and products claimed. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Consequently, the search has been carried out for those parts of the claims which appear to be supported and disclosed, namely those parts relating to the formulations mentioned in the examples.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-14, 18-40, 41-67 (part.), 68-72, 73-77 (part.), 101-103, 108-109, 114-117

Multiple unit dosage form, each unit comprising at least one core, a first coating layer and an outer layer  
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2. claims: 15-17, 41-67 (part.), 73-77 (part.), 104-107, 110-113

Multiple unit dosage form, each unit comprising at least one core, a first coating layer, one or more additional layers and an outer layer  
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3. claims: 78-81, 85-100

Multiple unit dosage form, each unit comprising at least one core and a coating layer  
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4. claims: 82-84

Combination drug comprising two different multiple unit dosage forms  
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## INTERNATIONAL SEARCH REPORT

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WO 03041692	A	22-05-2003	WO	03041692 A1 22-05-2003